

October 17, 2000

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Bill Hagenbucher  
2202-B Gateway Drive  
Opelika, Alabama 36801

Honorable Donna Shalala  
Secretary of Health and Human Svcs  
Room 615 F  
200 Independence Ave. SW  
Washington, D.C. 20201

Dear Ms. Shalala:

The Food and Drug Administration is in the process of proposing changes to the way hearing aids are sold that could put me out of business and impede access to hearing care services for millions of our nation's hearing impaired seniors.

I am a Board Certified, State Licensed, Hearing Instrument Specialist. For over 8 years, I have provided quality care services to thousands of our state's hearing impaired. Presently, all three members of the health hearing care (Hearing Instrument Specialist, Audiologist, and Physicians) are recognized as qualified entry points into the hearing health care delivery system. The rule FDA is advocating would allow audiologist, without any justification, to instill themselves as the sole entry point into hearing healthcare by allowing states to require expensive and non essential tests that only audiologist are qualified to perform.

Allowing audiologists an exclusive role in the hearing aid delivery system, without unqualified medical data evidencing that such a role is necessary for public health reasons, would severely undermine public health and safety and would increase costs to the hearing impaired.

The medical community, specifically the American Academy of Otolaryngologist (Ear, Nose and Throat) opposes this FDA proposal.  
I look forward to your response.

Cordially,

*Bill Hagenbucher*  
Bill Hagenbucher

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